

REMARKS

Claims 37-41 and 43-58 are pending in the present application. Claims 49-58 were previously withdrawn from consideration. Please note that claim 42 was previously cancelled (*see* Amendment filed March 27, 2009). By virtue of this response, claim 37 has been amended. Accordingly, claims 37-41 and 43-48 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. No new matter has been added.

Claim Rejections – 35 USC §112**Claims 37-41 and 43-48**

Claims 37-41 and 43-48 stand rejected under 35 U.S.C. §112, second paragraph as allegedly failing to particularly point out and distinctly claim the subject matter which is regarded as the invention. The Office Action alleges that there is insufficient antecedent basis for “the clips” in line 7 of claim 37, and that it is unclear if each clip comprises two tissue-piercing legs, or if one clip is one tissue-piercing leg and the other clip is the other tissue-piercing leg. The Office Action suggests that line 8 should be amended to recite that the tether passes “through the loops” (and not “through the loop”).

To expedite prosecution, Applicants have amended claim 37 as suggested by the Office Action. Claim 37 has been amended to recite that the tethered clip assembly comprises “at least two clips wherein the clips each comprise two tissue-piercing legs joined by a loop... and coupled to a tether that passes through the loops transversely to the legs.” Amended claim 37 clearly describes that each clip comprises two tissue-piercing legs. Applicants submit that claim 37 particularly points out and distinctly claims the subject matter which Applicants regard as their invention. Applicants request that the rejection of claims 37-41 and 43-48 under 35 U.S.C. §112, second paragraph be withdrawn.

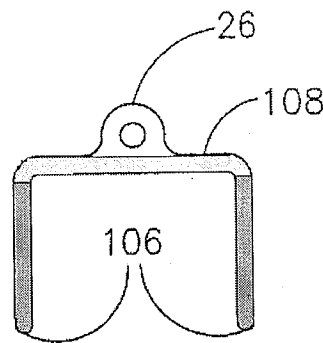
*Claim Rejections – 35 USC §103*Claims 37-44

Claims 37-44 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Pat. No. 5,984,933 to Yoon (“Yoon”) and further in view of WO 02/053011 A2 to Friedman (“Friedman”). The Office Action states that Yoon teaches the Applicants’ invention substantially as claimed, including a tethered clip assembly having a first deployed configuration comprising at least two clips separated by a first distance and coupled to a tether, and a second deployed configuration where the tether is under longitudinal tension and the first distance is reduced to a second distance. However, the Office Action concedes that Yoon fails to disclose that the clips comprise two tissue-piercing legs joined by a loop with the tether passing through the loop transversely to the legs, and that the two clips are in a closed tissue-piercing position when the tethered clip assembly is in both its first and second deployed configuration. The Office Action relies upon Friedman to cure this deficiency and states that that it would have been obvious for one of ordinary skill in the art to use the clip of Friedman with the delivery device of Yoon, as piercing the tissue is advantageous for several types of surgery to further secure the tissue. Applicants respectfully disagree with this rejection.

First, one of ordinary skill in the art at the time of the invention, given the disclosure of Yoon would not have any motivation to use the clips disclosed in Friedman with the delivery device of Yoon. The devices and methods disclosed in Yoon are entirely directed towards the delivery of knotting elements that are to be non-releasably engaged in a fixed position along the suture material, i.e., to have the same effect as tying a knot. The clips disclosed in Friedman are in no way capable of non-releasably engaging a suture. Replacing the knotting elements of Yoon with the clips of Friedman would render the Yoon device unsatisfactory for its intended purpose, since the Friedman clips are not capable of effecting a suture knot such that the clips are in a fixed position along the suture material. It is unclear what advantage would be provided by replacing the knotting elements of Yoon with clips that have tissue-piercing properties, since the piercing of tissue does not improve the ability of the clip to non-releasably engage a length of suture, and the ability to secure tissue

with tissue-piercing clips does not translate to any advantage in securing a suture knot, which is the intended use of the Yoon device.

Second, even if one were to use the clip of Friedman with the delivery device of Yoon as suggested by the Office Action, the resultant device would fail to satisfy each and every limitation of claim 37. Friedman fails to disclose a clip with two tissue-piercing legs joined by a loop. Friedman clearly states that each clip “has a pair of spaced-apart tissue-piercing ends 106 connected by a web portion 108... The web portion 108 of each anchor member 10 is provided with a suture-retaining form 26...” (see p. 10, ll. 21-22, 27-28). From this description, it is clear that the tissue-piercing ends of Friedman are not joined by a loop, but are instead connected by a web portion. As explained previously (e.g., on pp. 7-8 of the response mailed on October 5, 2009), the ring 26 is not a juncture between the two tissue-piercing ends 106, and therefore, the tissue-piercing ends 106 are not joined by the ring. In fact, neither of the legs even touches the ring 26. Friedman explicitly describes that the tissue-piercing ends 106 are connected by a web portion 108, and that the ring 26 is provided on the web portion. FIG. 12 is reproduced below and annotated with dark grey shading to indicate the legs 106 and light grey shading to indicate the web portion 108.



As seen here, the two legs 106 are connected by the web portion 108 and are not joined by the ring 26. The ring 26 surmounts the web 108, and is not in contact with either of the two legs 106. Since neither of the legs 106 even touches the ring 26, the legs 106 cannot be joined by the ring 26, as required by claim 37.

For at least the above reasons, a rejection of independent claim 37 under 35 U.S.C. §103(e) cannot stand. Applicants respectfully request the rejection of the pending claims be withdrawn, and submit that claims 37-41 and 43-44 are patentable.

Claims 45, 46 and 48

Claims 45, 46 and 48 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Yoon and Friedman, as applied to claim 37 above, in view of U.S. Pat. No. 5,524,630 to Crowley ("Crowley").

Yoon and Friedman were discussed in detail above with respect to claim 37 (from which claims 45, 46, and 48 depend), where it was established that the combination of Yoon and Friedman fail to teach or disclose clips that have and two tissue-piercing legs joined by a loop. Furthermore, modifying Yoon with Friedman would render the Yoon device unsatisfactory for its intended purpose, since the Friedman clips are not capable of effecting a suture knot. Crowley fails to cure these deficiencies. As such, Applicants respectfully request that the rejection of claims 45, 46, and 48 under 35 U.S.C. §103(a) be withdrawn.

Claim 47

Claim 47 stands rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Yoon, Friedman and Crowley as applied to claim 45 above, further in view of U.S. Pat. No. 5,766,240 to Johnson ("Johnson").

Yoon and Friedman were discussed in detail above with respect to claim 37 (from which claim 47 depends), where it was established that the combination of Yoon and Friedman fail to teach or disclose clips that have two tissue-piercing legs joined by a loop. Furthermore, modifying Yoon with Friedman would render the Yoon device unsatisfactory for its intended purpose, since the Friedman clips are not capable of effecting a suture knot. Both Crowley and Johnson fail to cure these deficiencies. As such, Applicants respectfully request that the rejection of claim 47 under 35 U.S.C. §103(a) be withdrawn.

Double PatentingClaims 37-41 and 43-48

Claims 37-41 and 4-48 stand rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1-36 of U.S. Patent No 6,986,775 (the '775 patent). Applicants acknowledge that the Examiner has received the terminal disclaimer submitted for the '775 patent, and that no further action is needed from Applicants at this time.

Claims 37-41 and 43-48

Claims 37-41 and 43-48 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-100 of copending Application No. 11/237,461, claims 37-46 of copending Application No. 12/131,840, and claims 58-94 of copending Application No. 12/132,375.

Applicants will consider filing terminal disclaimers to reference each of the patent applications listed above after receiving an indication that each of the currently rejected claims is allowable. Until then, Applicants have no real way of assessing the merits of the double patenting rejection or determining whether the filing of a terminal disclaimer is appropriate.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

Any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby.

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child, or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and

authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 578492000510. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: August 16, 2010

Respectfully submitted,

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